

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

An RCE, requesting entry of the after final response filed June 8, 2004, was submitted with this response.

Applicants thank Examiner Davis for the telephone discussions held August 3 and August 9, 2004 regarding the status of the after final response filed June 8, 2004 and the arguments therein.

I. CLAIM STATUS & AMENDMENTS

Claims 24-29 were pending in this application when last examined. These claims stand rejected.

New claims 30-35 have been added.

Support for new claims 30-35 directed to "treatment of cancer" can be found in the specification, for example, at page 3, lines 4-7, page 4, lines 1-5, page 8, lines 1-20, page 13, lines 8-12 and original claims 1-23.

Therefore, no new matter has been added by this amendment.

Claims 24-35 are now pending in this application.

II. REJECTION UNDER 35 U.S.C. § 103

Claims 24-29 were rejected under 35 U.S.C. § 103(a), as obvious over Sekine et al., Human Cell, Vol. 7, No. 3, pp. 121-124 (1994) in view of Chakravarty et al., Current Science, Vol. 73, No. 2, pp. 201-203 (1997). See page 2 of the Advisory Action dated August 17, 2004 and pages 2-4 of the final Office Action dated December 8, 2003.

Applicants respectfully submit that the amendments in the response filed June 8, 2004 overcome this rejection as applied to the amended and new claims for the reasons noted in the prior response and for the following reasons.

Sekine and Chakravarty fail to disclose and/or suggest each and every element of the claimed invention, namely, the prevention of recurrence of cancer for five years.

The claimed invention relates to a curative method for the prevention of the recurrence of liver cancer and cancer in general by administering activated lymphocytes in combination with a surgical procedure to prevent the recurrence of cancer for at least five years.

However, as discussed in section II on pages 3-6 of the prior response, Sekine and Chakravarty fail to disclose and/or suggest the prevention of recurrence of cancer for five years. This is even acknowledged at page 4, lines 1-2 of the final Office Action dated December 8, 2003, wherein it is indicated that Sekine does not disclose the prevention of recurrence of cancer for at least five years. Similarly, Chakravarty fails to disclose the prevention of recurrence of cancer for five years. In fact, Chakravarty fails to discuss the efficacy of prevention of recurrence. Accordingly, neither reference discloses nor suggests the prevention of recurrence of cancer for five years. Thus, Sekine and Chakravarty cannot be said to disclose and/or suggest each and every element of the claimed invention.

In addition, Sekine and Chakravarty lack a reasonable expectation for the successful prevention of recurrence of cancer for five years.

In this regard, it is disclosed at line 10 on page 14 of the instant specification that the recurrence rate of cancer following surgical treatment is quite high. For instance, hepatocellular carcinoma often recurs within a short period of time and at a high rate, even after radical surgical operations. Also, as disclosed at lines 4-7 on page 2, of the specification, activated lymphocytes have been used alone under conventional techniques with poor efficacy for preventing the recurrence of cancer. The efficacy of activated lymphocytes under conventional techniques alone is a short period of time, approximately, two years.

Sekine merely describes the protocol and initial data from a clinical trial involving a two year study. The results of Sekine's two year study fail to suggest the prevention of the recurrence of cancer for five years.

In fact, Sekine at page 5, lines 5-10 discloses that the recurrence rate for liver cancer is 33% in the first year, 57% in the second year, 70% in the third year, and that no effective preventative method is known. In this sense, Sekine teaches away from the claimed invention, i.e., away from prevention for 5 years. Thus, based on the teachings of Sekine and the general knowledge in the art, no reasonable expectation of success existed at the time of the publication of Sekine for the prevention of recurrence of cancer for five years.

Chakravarty fails to rectify the deficiencies in Sekine. Chakravarty simply fails to disclose and/or suggest the prevention of recurrence of cancer for any length of time.

Again, the prevention of recurrence for two years is not suggestive for five years and the high recurrence rates disclosed in Sekine (33% in the first year, 57% in the second year, 70% in the third year) fail to provide a reasonable expectation of success for arriving at the claimed invention.

Moreover, notwithstanding that the claimed invention is not obvious over the cited references, the data of the instant invention amounts to surprising and unexpected results in view of the state of the art as evidenced by Sekine and the general knowledge in the art. As demonstrated at page 13, lines 1-7 of the specification, the efficacy of the instant invention for the prevention of cancer is at least five years. Five years far exceeds the two years disclosed in Sekine.

During the telephone discussion with the Examiner, the Examiner questioned whether the prevention of the reoccurrence of liver cancer for five years amounts to surprising and unexpected results, because cancer patients are allegedly expected to live at least five years following a surgical procedure for removal of the cancer. However, this assertion is inconsistent with the high recurrence rates disclosed in Sekine (33% in the first year, 57% in the second year, 70% in the third year). Thus, it would appear that the claimed invention does indeed achieve surprising and unexpected results in view of the state of the art as evidenced by the cited prior art cited references.

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December 8, 2004

Therefore, the rejection of claims 24-29 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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